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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,801	01/17/2006	Jean-Francois Garbe	0515-1108	4287

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EXAMINER	
NGUYEN, TUAN VAN	
ART UNIT	PAPER NUMBER
3731	

NOTIFICATION DATE	DELIVERY MODE
04/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/530,801	GARBE, JEAN-FRANCOIS	
	Examiner	Art Unit	
	TUAN V. NGUYEN	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16 and 19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *25* is/are allowed.

6)☒ Claim(s) *11-16 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 11-16 and 19-25 are pending in this present applicant and they are presented for examination.
2. This Office action is in response to the Supplemental Appeal Brief filed on 01/14/2010.

Reopening of Prosecution After Appeal

3. In view of the Supplement Appeal Brief filed on 14 January, 2010, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below:

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below (please see last page):

Response to Arguments

4. Applicant's arguments in the Supplemental Appeal Brief have been fully considered but they are moot in view of new ground of rejection.

Claim Rejections - 35 USC § 101

5. The 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 23 is rejected under 35 U.S.C. 101 because it recites the limitation of "a body duct" thus the claim positively claims the human body or portions thereof as part of the claimed subject matter.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

    1. Determining the scope and contents of the prior art.
    2. Ascertaining the differences between the prior art and the claims at issue.
    3. Resolving the level of ordinary skill in the pertinent art.
    4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. **Claims 13, 22, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldsteen et al (U.S. 5,941,908) in view of Piplani et al. (U.S. 6,132,459) and further in view of Schulsinger et al (U.S. 5,897,572).**

10. Referring to **claims 22, 23, and 24**, Goldsteen et al disclose (Figs. 5 and 6) a prosthesis 20, tubular connectors 30 or mesh sleeve located at each end of the prosthesis. The tubular connectors, each includes transfixion pins 36 positioned at substantially regular interval about a circumference of the tubular connector 30 and at an angle or substantially perpendicular to the outer surface of the tubular connector 30 or sleeve. Figures 1 and 3 of Goldsteen's drawings show the tubular connectors 30 or mesh sleeve capable of radial expansion between a stable minimal-diameter configuration and a final after-expansion configuration that is also stable (Col. 2: 45-55 and Col. 3: 44-48).

11. Still referring to **claims 22, 23, and 24**, Goldsteen discloses the invention substantially as claimed except for disclosing the transfixion pins positioned about a circumference proximate each sleeve end. However, Piplani discloses the transfixion pins are positioned on each sleeve end to prevent distal and proximal

migration of the leg (Figs. 8 and Col. 7: 45-58). It would have been obvious to one of ordinary skill in the art to provide the transfixion pins 36 on each sleeve end to the tubular connectors 30 of Goldsteen in order to gain the advantage as taught by Piplani. The modified device of Goldsteen discloses the invention substantially as claimed except for specifically disclosing the transfixion pins 36 includes a circular base section extending to a trihedral-shaped end portion.

12. Still referring to **claims 22, 23, and 24**, however, Schulsinger discloses (see Figs 1 and 7) a needle having a circular portion extending to a trihedral-shaped end portion thereby reducing trauma to the tissue being penetrated as the cutting edges 16 creates a cleaner incision with less tearing of the tissue (see col. 2, lines 25-28). It would have been obvious to one of ordinary skill in the art to form the transfixion pin 36 of Goldsteen with a circular base and trihedral-shaped end as disclosed by Schulsinger in order to gain the advantage as taught by Shulsinger.

13. Still referring to **claims 22, 23, and 24,** with respect to the limitation of "length sufficient to pass entirely through a wall of the body duct". Examiner contends that the transfixion pins 36 of the modified device of Goldsteen having a length that is capable to pass entirely through a wall of a body duct of a coronary artery because it is old and well known in the art that the wall thickness of a blood vessels in a body corresponding to the diameter of the blood vessel. The wall thickness of coronary artery certainly thinner as compare to the wall thickness of the abdominal aorta.

14. Referring to **claim 13**, due to lack of criticality in the specification, expanding the sleeve to a final diameter which is greater than twice its initial diameter was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to expanding the sleeve to twice the diameter or just under twice the diameter. Noting that Goldsteen discloses the connector or sleeve capable to expand from a small initial diameter to a final diameter that larger than initial diameter (Figs. 1 and 3). It would have been obvious to one having ordinary skill in the art to design the modified connector of Goldsteen to have a ratio of a final diameter to an initial diameter is greater than 2, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

15. **Claims 11-12 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldsteen et al. in view of Piplani et al., and Schulsinger et al. as applied to claim 22 above and further in view of Martin (U.S. 5,397,355)**

16. Referring to **claims 11-12**, the modified device Goldsteen discloses the invention substantially as claimed except for disclosing the limitations as claimed in claims 11 and 12. However, Martin discloses such an arrangement of the mesh and the barbs on his endoluminal graft connector (Fig. 5 and Col. 1 to Col.3). Apparently, the plurality of barbs and diamond-shaped mesh was used to allow the connector to expand with lesser force and to increase the security of the attachment of the

connector and the vessel together (see Summary of the Invention). Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the design of diamond-shaped and location of the barbs as disclosed by Martin into the tubular structure as disclosed by Goldsteen in order to gain the advantage as taught by Martin.

17. Referring to **claims 19-20**, it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3. Piplani discloses the transfixion pin can be attached to the tubular connector by bonded (Col. 7: 40-45). Further, Duhaylongsod et al. (U.S. 6,241,741) discloses the barbs 36 are attached to the device by either soldering or gluing (see Fig. 1A and col. 4, lines 40-45). Therefore, it would have been obvious to use method of attaching the barbs to the device as disclosed by Duhaylongsod to the modified device as disclosed by Goldsteen because the aforementioned attaching methods are old and well known in the art. It has been held that choosing from a finite number of identified, predictable solution, with a reasonable expectation of success it is old and well known in the art.

18. **Claims 14, 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldsteen et al. in view of Piplani et al., Schulsinger et al., and Martin as applied to claim 12 above and further in view of Derowe et al (U.S. 7,022,131).**

19. Referring to **claim 14**, the modified device of Goldsteen discloses the invention substantially as claimed except for the limitations in claim 14. However, Derowe discloses (see col. 60, lines 5-25) not all the spikes of his coupler of mesh sleeve have the same cross section and/or sharpness and/or tip shape and/or have different bending locations. Due to lack of criticality in the specification, the transfixion pins on each end of the sleeve are straight, and wherein the intermediate transfixion pins are slightly curved was shown to solve no particular problem, serve no particular purpose and provide no additional benefit as opposed to the modified design of Goldsteen. It has been held that simple substitution of one known element for another to obtain predictable results is old and well in the art, therefore, it would have been obvious to one of ordinary skill in the art to try the design of the spikes as disclosed by Derowe into the modified device of Goldsteen.

20. Referring to **claims 15 and 21**, noting that Martin disclose the barbs positioned at an angle and Goldsteen et al also disclose (Figs. 5 and 6) the transfixion pins positioned at an angle or substantially perpendicular to the outer surface of the connector or coupler or sleeve. It would have been obvious to one having ordinary skill in the art to design the angle of the barbs of the modified connector of

Goldsteen to have an angle of 5 degrees or a range of between 0 degrees and 10 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

21. **Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldsteen et al. in view of Piplani et al., Schulsinger et al., and Martin as applied to claims 12 above and further in view of Chobotov et al. (US 2003/0120338).**

22. The modified device of Goldsteen discloses the invention substantially as claimed except for the length of each barb can vary within a single device. However, Chobotov discloses such a design (see page 6, paragraph 80). Apparently the design intended is so that the barb lengths can be of the appropriate length for the thickness of the multiple or single layers that it has to pierce through and to prevent the damage to the surrounding tissue juxtaposed t the anastomosis site. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate the design of barbs as disclosed by Chobotov to the modified device of Goldsteen so that it to would have the same advantage.

Allowable Subject Matter

23. Claim 25 allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
4/22/10